

CLAIMS

We claim:

- 1) A pharmaceutical composition comprising:
 - a) a COX-II inhibitor;
 - b) a muscle relaxant; and
 - c) at least one pharmaceutical excipient.
- 5 2) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor binds COX-II receptors selectively over COX-I receptors.
- 3) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor binds 10 COX-II receptors specifically.
- 10 4) The pharmaceutical composition of claim 1, wherein the weight ratio of COX-II inhibitor to muscle relaxant varies from (12.5:2.2) to (50:8).
- 5) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor is selected 15 from the group consisting of central muscle relaxants and neuromuscular blocking agents.
- 6) The pharmaceutical composition of claim 1, wherein the at least one pharmaceutical excipient is independently selected from the group consisting of an acidifying agent, adsorbents, alkalizing agent, antioxidants, buffering agent, colorant, flavorant, sweetening agent, tablet antiadherent, tablet binder, tablet and capsule diluent, tablet 20 direct compression excipient, tablet disintegrant, tablet glidant, tablet lubricant, tablet or capsule opaquant, plasticizer, surface active agent, solvent, oil, soap, detergent, and tablet polishing agent.
- 7) (Amended) The pharmaceutical composition of claim 1, wherein the muscle relaxant 25 is selected from the group consisting of alcuronium, alosetron, aminophylline, baclofen, carisoprodol, chlorphenesin, chlorphenesin carbamate, chlorzoxazone, chlormezanone, cyclobenzaprine, dantrolene, decamethonium, diazepam, dyphylline, eperisone, ethaverine, gallamine triethiodide, hexafluorenium, mephenesin, metaxalone, methocarbamol, metocurine iodide, orphenadrine, pancuronium, papaverine, pipecuronium, pridinol, succinylcholine, theophylline, tizanidine,

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tolperisone, tubocurarine, vecuronium, idrocilamide, ligustilide, cnidilide, and senkyunolide.

8) (Amended) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor is selected from the group consisting of rofecoxib, celecoxib, flosulide, NS-398, DUP-697, meloxicam, 6-methoxy-2-naphthylacetic acid, nabumetone, etodolac, nimesulide, SC-5766, SC-58215, T-614, and combinations thereof.

10) A pharmaceutical dosage form comprising:

- a) a therapeutically effective amount of a COX-II inhibitor;
- b) a therapeutically effective amount of a muscle relaxant; and
- c) at least one pharmaceutical excipient.

11) The pharmaceutical dosage form of claim 10, wherein the dosage form is selected from the group consisting of a gel, cream, ointment, pill, tablet, capsule, liquid, suspension, osmotic device, bead, granule, spheroid, particulate, paste, prill, reconstitutable solid, powder, and injectible liquid.

15) 12) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form independently provides a controlled, delayed, sustained, immediate, timed, slow or rapid release of each of the COX-II inhibitor and the muscle relaxant when exposed to an aqueous environment.

20) 13) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides therapeutically effective plasma levels of the COX-II inhibitor for a period up to at least about 12 hours after administration to a subject.

25) 14) (Amended) The pharmaceutical dosage form of claim 10, wherein after administration to a subject the dosage form provides therapeutically effective plasma levels of the muscle relaxant for a period of administration sufficient to enhance the therapeutic benefit provided by the COX-II inhibitor.

15) The pharmaceutical dosage form of claim 10, wherein the pharmaceutical dosage form is adapted for oral, buccal, ocular, otic, gastrointestinal, dermal, rectal, vaginal, cervical, intrauterine, epidermal, transdermal, implant, mucosal, parenteral, sublingual, nasal, or pulmonary delivery.

16) (Amended) The pharmaceutical dosage form of claim 10, wherein the muscle relaxant is selected from the group consisting of alcuronium, alosetron, aminophylline, baclofen, carisoprodol, chlorphenesin, chlorphenesin carbamate, chlorzoxazone, chlormezanone, cyclobenzaprine, dantrolene, decamethonium, diazepam, dyphylline, eperisone, ethaverine, gallamine triethiodide, hexafluorenium, mephenesin, metaxalone, methocarbamol, metocurine iodide, orphenadrine, pancuronium, papaverine, pipecuronium, pridinol, succinylcholine, theophylline, tizanidine, tolperisone, tubocurarine, vecuronium, idrocilamide, ligustilide, cnidilide, and senkyunolide.

10 17) (Amended) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor is selected from the group consisting of rofecoxib, celecoxib, flosulide, NS-398, DUP-697, meloxicam, 6-methoxy-2-naphthylacetic acid, nabumetone, etodolac, nimesulide, SC-5766, SC-58215, T-614, and combinations thereof.

15 18) (Amended) The pharmaceutical dosage form of claim 10, wherein each drug is released rapidly and the dosage form provides therapeutically effective levels of each drug for a period of at least 12 hours after administration to a subject.

19) The pharmaceutical dosage form of claim 18, wherein the period is about 12 to 60 hours.

20 20) The pharmaceutical dosage form of claim 19, wherein the period is about 12 to 30 hours.

21) The pharmaceutical dosage form of claim 19, wherein the period is about 18 to 48 hours.

25 22) (Amended) The pharmaceutical dosage form of claim 10, wherein after administration to a subject the plasma level of the COX-II inhibitor or muscle relaxant is dependent upon the plasma level of the muscle relaxant or COX-II inhibitor, respectively.

23) (Amended) The pharmaceutical dosage form of claim 10, wherein after administration to a subject the plasma level of the COX-II inhibitor or muscle relaxant is independent of the plasma level of the muscle relaxant or COX-II inhibitor, respectively.

24) The pharmaceutical dosage form of claim 10, wherein the dosage form provides therapeutic plasma levels for the muscle relaxant in an amount sufficient to provide a therapeutic benefit to a subject to whom it is administered.

25) (Amended) The pharmaceutical dosage form of claim 10, wherein after administration to a subject the dosage form provides therapeutic plasma levels for the COX-II inhibitor in the range of about 90 ng to about 300 ng per ml of plasma in the subject.

26) (Amended) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor and muscle relaxant are released sequentially after exposure to an aqueous environment.

10 27) (Amended) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor and muscle relaxant are released concurrently after exposure to an aqueous environment.

28) (Amended) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor and muscle relaxant are released in spaced apart periods of time after exposure to an aqueous environment.

15 29) (Amended) The pharmaceutical dosage form of claim 10, wherein each drug is independently released according to a rapid, immediate, controlled, sustained, slow, timed, targeted, pseudo-first order, first order, pseudo-zero order, zero-order, and/or delayed release profile after exposure to an aqueous environment.

20 30) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a controlled release of the COX-II inhibitor and a controlled release of the muscle relaxant after exposure to an aqueous environment.

31) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a controlled release of the COX-II inhibitor and a rapid release of the muscle relaxant after exposure to an aqueous environment.

25 32) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a controlled release of the muscle relaxant and a rapid release of the COX-II inhibitor after exposure to an aqueous environment.

33) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the COX-II inhibitor and of the muscle relaxant after exposure to an aqueous environment.

34) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the muscle relaxant and a delayed but rapid release of the COX-II inhibitor after exposure to an aqueous environment.

35) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the muscle relaxant and a timed but controlled release of the COX-II inhibitor after exposure to an aqueous environment.

10 36) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the COX-II inhibitor and a delayed but rapid release of the muscle relaxant after exposure to an aqueous environment.

37) (Amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a rapid release of the COX-II inhibitor and a timed but controlled release of the muscle relaxant after exposure to an aqueous environment.

15 38) The pharmaceutical dosage form of claim 10, wherein the weight ratio of COX-II inhibitor to muscle relaxant varies from 12.5:2.2 to 50:8.

40) (New) A pharmaceutical composition comprising:

20 a) a COX-II inhibitor selected from the group consisting of rofecoxib, celecoxib, flosulide, NS-398, DUP-697, meloxicam, 6-methoxy-2-naphthylacetic acid, nabumetone, etodolac, nimesulide, SC-5766, SC-58215, T-614, and combinations thereof;

25 b) a muscle relaxant selected from the group consisting of alcuronium, alosetron, aminophylline, baclofen, carisoprodol, chlorphenesin, chlorphenesin carbamate, chlorzoxazone, chlormezanone, cyclobenzaprine, dantrolene, decamethonium, diazepam, dyphylline, eperisone, ethaverine, gallamine triethiodide, hexafluorenium, mephenesin, metaxalone, methocarbamol, metocurine iodide, orphenadrine, pancuronium, papaverine, pipecuronium, pridinol, succinylcholine, theophylline, tizanidine, tolperisone, tubocurarine, vecuronium, idrocilamide, 30 ligustilide, cnidilide, and senkyunolide and combinations thereof; and

c) at least one pharmaceutical excipient.

41)(New) The composition of claim 40, wherein the at least one pharmaceutical excipient is independently selected from the group consisting of an acidifying agent, adsorbent, alkalizing agent, antioxidant, buffering agent, colorant, flavorant, sweetening agent, tablet antiadherent, tablet binder, tablet and capsule diluent, tablet 5 direct compression excipient, tablet disintegrant, tablet glidant, tablet lubricant, tablet or capsule opaquant, plasticizer, surface active agent, solvent, oil, soap, detergent, and tablet polishing agent.

42)(New) The composition of claim 41, the weight ratio of COX-II inhibitor to muscle relaxant varies from (12.5:2.2) to (50:8).

10 43)(New) The composition of claim 40, wherein the COX-II inhibitor and muscle relaxant are independently provided in each occurrence in controlled, sustained, immediate, timed, slow or rapid release form.

44)(New) The composition of claim 43, wherein at least one of the COX-II inhibitor and muscle relaxant are independently further provided in each occurrence in delayed or 15 targeted release form.

45)(New) The composition of claim 40, wherein at least one of the COX-II inhibitor and muscle relaxant are independently provided in each occurrence in pseudo-first order, first order, pseudo-zero order, or zero order release form.

46)(New) A pharmaceutical dosage form comprising the pharmaceutical composition of 20 claim 40.

47)(New) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 41.

48)(New) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 42. —

25 49) (New) A pharmaceutical composition comprising:
a) a COX-II inhibitor selected from the group consisting of rofecoxib and celecoxib;
b) pridinol; and
c) at least one pharmaceutical excipient.

50)(New) The pharmaceutical composition of claim 49, wherein the at least one pharmaceutical excipient is independently selected from the group consisting of an acidifying agent, adsorbent, alkalizing agent, antioxidant, buffering agent, colorant, 30

flavorant, sweetening agent, tablet antiadherent, tablet binder, tablet and capsule diluent, tablet direct compression excipient, tablet disintegrant, tablet glidant, tablet lubricant, tablet or capsule opaquant, plasticizer, surface active agent, solvent, oil, soap, detergent, and tablet polishing agent.

5 51) (New) The composition of claim 49, the weight ratio of COX-II inhibitor to pridinol varies from (12.5:2.2) to (50:8).

52) (New) The composition of claim 49, wherein the COX-II inhibitor and pridinol are independently provided in each occurrence in controlled, sustained, immediate, timed, slow or rapid release form.

10 53) (New) The composition of claim 52, wherein at least one of the COX-II inhibitor and pridinol are independently further provided in each occurrence in delayed or targeted release form.

54) (New) The composition of claim 49, wherein at least one of the COX-II inhibitor and pridinol are independently provided in each occurrence in pseudo-first order, first order, pseudo-zero order, or zero order release form.

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